Comprehensive ambulatory monitoring during immunotherapy in patients with advanced melanoma: a prospective trial (CAMP-IT)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22326

Source
NTR

Brief title
CAMP-IT

Health condition

melanoma

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Amsterdam, The Netherlands
Source(s) of monetary or material Support: BMS

Intervention

Outcome measures

Primary outcome

feasibility in terms of (i) participation rates, (ii) wear-time, (iii) compliance rates with in-app

questionnaires and temperature measurements, and (iv) satisfaction with the platform.

Secondary outcome

Secondary exploratory outcomes include associations between CAMP-derived parameters and clinical outcomes: performance status (PS), HRQoL (EORTC QLQ-C30), unplanned hospitalizations, adverse events, and 1-year survival outcomes. PS and HRQoL will be rated at baseline, mid-study, and end-of-study. The occurrence of disease- and treatment-related adverse events will be documented up to 12 months from baseline. Survival outcomes will be compared to a propensity score matched group from the Netherlands Cancer Registry.

Study description

Background summary

The emergence of immune checkpoint inhibitors has improved survival outcomes for patients with advanced melanoma. However, these treatment modalities are also associated with specific immune-related toxicities. These are often reversible after prompt recognition and initiation of appropriate management, but can result in severe morbidity and hamper health-related quality of life (HRQoL) if left undetected. Hence, accurate and regular monitoring of these patients is critical. Recent advances in mHealth technologies and the rapidly expanding armamentarium of wearable devices allow for real-time objective (vital signs and physical activity) data and patient-reported outcome measurement (PROMs) collection and, hence, serve this purpose. We hypothesize that collection of real-time objective data adds to the early detection of disease- and treatment-related adverse events. The primary objective of this study is to determine the feasibility of collecting real-time PROMs, vital signs, and physical activity data in advanced melanoma patients receiving immunotherapy using a comprehensive ambulatory monitoring platform (CAMP) that consists of a smartphone app, activity monitor, digital thermometer, and online dashboard for physicians. In this prospective multi-center trial, patients (n=50) with advanced melanoma, scheduled to receive immunotherapy with immune checkpoint inhibitors, and with access to a smartphone are eligible for inclusion. Consenting patients will be asked to wear a FitBit Versa 2.0 during waking hours, collect daily temperature measurements using a Withings Smart Temporal thermometer, and answer weekly toxicity questionnaires (NCI PRO-CTCAE) using the smartphone app for the duration of the study (12 weeks). Primary outcome is feasibility in terms of (i) participation rates, (ii) wear-time, (iii) compliance rates with in-app questionnaires and temperature measurements, and (iv) satisfaction with the platform. Secondary exploratory outcomes include associations between CAMP-derived parameters and clinical outcomes: performance status (PS), HRQoL (EORTC QLQ-C30), unplanned hospitalizations, adverse events, and 1-year survival outcomes. PS and HRQoL will be rated at baseline, mid-study, and end-of-study. The occurrence of disease- and treatment-related adverse events will be documented up to 12 months from baseline. Survival outcomes will be compared to a propensity score matched group from the Netherlands Cancer Registry.

Study objective

It is feasibility to collect activity data, vital signs, and PROMS using a comprehensive online monitoring platform that consists of a wearable activity monitor, digital thermometer, and smartphone-app in patients with advanced melanoma undergoing immunotherapy.

Study design

T0: start immunotherapy and connection to the Comprehensive online monitoring platform
T1: (+6weeks) mid-study
T2: (+12 weeks) end-of-study
T3: (+1 year)

Intervention

Comprehensive ambulatory monitoring platform

Contacts

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Eligibility criteria

Inclusion criteria

• >18 years
• scheduled to receive immunotherapy with ipilimumab, nivolumab, or pembrolizumab
• Ambulatory without use of walking aids
• Access to device that has the capability to sync the wearable activity monitor and digital thermometer
• Proper understanding of the Dutch language
• Have an understanding, ability, and willingness to fully comply with study procedures and

restrictions
• Ability to consent

Exclusion criteria

• History of allergy to surgical steel or elastomer/rubber
• Using a pacemaker, implantable cardiac defibrillator, neurostimulator, hearing aids, cochlear implants, or other electronic medical equipment
• Permanent or temporary changes to the skin of the wrist (e.g. tattoos, scar tissue) that might impact heart rate sensor performance
• Incapability to use digital devices

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-02-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8827
Other	METC AMC : W20_254 # 20.289

Study results